Availability and Use of Thimerosal-Free Vaccines

1. Which vaccines do not contain thimerosal?

Today, all routinely recommended licensed children's vaccines that are currently being manufactured for the U.S. market contain no thimerosal or only trace amounts (those with a concentration of less than 0.0002% contain what is considered "trace," insignificant amounts). For more information on thimerosal content in some currently manufactured U.S. licensed vaccines, go to www.fda.gov/cber/vaccine/thimcnt.htm.

Influenza (flu) vaccines and tetanus and diphtheria vaccines (Td and DT) are not available without thimerosal.

2. Why weren't thimerosal-containing vaccines taken off the market?

Voluntary and mandatory recalls of drug products are the responsibility of the Food and Drug Administration (FDA). A mandatory recall requires that the product present "an imminent or substantial hazard to the public health." Current scientific data have not established that products containing thimerosal, when used within prescribed limits as a preservative, create an imminent or substantial hazard to public health or are in violation of FDA laws or regulations, and therefore do not justify such a recall.

3. Should immunization providers stop using licensed pediatric vaccines that contain thimerosal?

No. Immunization providers should use the vaccines available in their stock. The use of vaccines should continue according to the currently recommended schedule. The risks of not vaccinating children on time far outweigh the risk, if any, of exposure to thimerosal-containing vaccines which may still be available. Because of the expiration date of current vaccines, it is anticipated that by the second quarter of 2002, only pediatric thimerosal preservative-free vaccines will be available. —

4. What is the availability of the thimerosal-free hepatitis B vaccine?

All hepatitis B vaccines intended for use in infants and children are now free of thimerosal as a preservative, and an adequate supply of these vaccines is now available for all infant and childhood vaccinations. This vaccine should be administered to all newborn infants and is a major cornerstone in the prevention of a potentially fatal disease in children and adults.

5. What are CDC recommendations for initiating the hepatitis B vaccine series for newborn infants?

The initiation of the hepatitis B vaccine series should be started for all newborn infants whether they are considered at low or high risk for the transmission of the hepatitis B virus. This recommendation has been re-instated as a result of the increased availability of the hepatitis B vaccines without thimerosal as a preservative.

In July 1999, a joint American Academy of Pediatrics and Public Health Service statement recommended administering thimerosal-free vaccines to newborn infants at risk for perinatal transmission of the hepatitis B virus and postponing this vaccine for newborns who are not

at high risk. This recommendation was made due to the inadequate supplies of vaccines at the time but led some hospitals to stop hepatitis B vaccinations to all newborns. The recently increased supplies of the thimerosal-free hepatitis B vaccine means that all hospitals can now administer the hepatitis B vaccine to all newborn infants and should resume doing so as soon as possible.

The hepatitis B vaccine is safe and effective. It can prevent chronic hepatitis B virus infection that can develop in approximately 90% of those infants infected with the virus at birth, and decrease the risk of premature death among 25% of these infected infants who will suffer from either hepatitis B-related liver cancer or cirrhosis. The routine administration of the hepatitis B vaccine can protect infants, children and adults from these types of diseases.

6. Are there adequate supplies of thimerosal-free vaccines to meet national demand?

Yes, there are sufficient supplies of thimerosal-free vaccines to assure an uninterrupted supply to meet national demand. Because of the expiration date of current vaccines, it is believed that few of those containing thimerosal preservative are still being administered.